

Remarks

Claims 1-10, 12-20, and 22-29 are pending. Claims 11 and 21 were previously canceled. Claims 1-10, 12-20, and 22-29 are rejected.

Claims 1, 12, and 22 are amended to incorporate and clarify the limitations previously recited in these claims. The amendment to these claims therefore present no new issue for examination.

Rejections under 35 U.S.C. § 102

Claims 1-10, 12-20, and 22-29 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Hossainy (US 6,926,919).

Claim 1 defines a method for fabricating a coating for an implantable medical device. The method comprises (a) forming a first layer of the coating on the device, and **(b) forming a second layer of the coating on at least a portion of the first layer. The first layer includes at least one hydrophobic polymer and at least one hydrophilic polymer. The second layer is water soluble and includes at least one hydrophilic or amphiphilic polymer.** The hydrophobic polymer and the hydrophilic polymer in the first layer have a mass ratio between about 49:1 and about 19:1.

Hossainy discloses a coating for an implantable medical device comprising a hydrophobic and a hydrophilic polymer (col. 2, lines 35-40). The mass ratio between hydrophilic and hydrophobic polymers in the coating can be typically between about 1:100 and 1:9 (col. 3, lines 16-21). However, **Hossainy has no description of coating that includes a second layer over the first layer, the second layer being water soluble.** As the Examiner correctly notes, Hossainy discloses a stent having a coating including a

blend of a hydrophobic and hydrophilic polymer, and treating the coating with a stimulus for enriching a region close to the outer surface of the coating with a hydrophilic polymer to cause the region of the coating to have a higher content of the hydrophilic component than the hydrophobic component. However, **this embodiment of stent disclosed by Hossainy does not lead to forming a second layer of polymer that is water soluble. Indeed, a layer of poly(ethylene-co-vinyl alcohol) described in Hossainy for this embodiment is not a water soluble.**

In sum, claim 1 is patentably allowable over Hossainy under 35 U.S.C. 102(e). Claims 2-10 depend from claim 1 and are patentably allowable over Hossainy under 35 U.S.C. 102(e) for at least the same reason.

Claim 12 defines a coating for an implantable medical device. The coating comprises (a) a first layer disposed on the device, the first layer including at least one hydrophobic polymer and at least one hydrophilic polymer; and (b) a second layer disposed on at least a portion of the first layer. **The second layer is water soluble and includes at least one hydrophilic or amphiphilic polymer.** The hydrophobic polymer and the hydrophilic polymer in the first layer have a mass ratio between about 49:1 and about 19:1. As discussed above, **Hossainy does not disclose a coating as defined by claim 12 that includes a layer of polymer that is water soluble.** Claim 12 is therefore patentably allowable over Hossainy under 35 U.S.C. 102(e). Claims 13-20 depend from claim 12 and are patentably allowable over Hossainy for at least the same reason.

Claim 22 defines a method of surface modification of a coating that includes forming a second layer that includes at least one hydrophilic or amphiphilic polymer over a first layer defined therein, **the second layer being water soluble.** For reasons

discussed above, claim 22 is patentably allowable over Hossainy under 35 U.S.C. 102(e).
Claims 23-29 depend from claim 22 and are patentably allowable over Hossainy for at least the same reason.

CONCLUSION

The amendment to claims 1, 12 and 22 does not present any new issue for examination. Withdrawal of the rejection and allowance of the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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Respectfully submitted,

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